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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/486,904	03/03/2000	JOHN R. SNYDER	3220-66107	9526

23643 7590 02/27/2003

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EXAMINER

HELMER, GEORGIA L

ART UNIT PAPER NUMBER

1638

DATE MAILED: 02/27/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application N .

09/486,904

Applicant(s)

SNYDER ET AL.

Examiner

Georgia L. Helmer

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 11 December 2002 .
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 9 and 20-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9 and 20-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ .
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_ .
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_ .

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1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 16 October 2002 has been entered.

Claims 9 and 20-24 are pending, and are examined in this Office Action.

***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.



3. Claims 9 and 20-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 9 and 23,

- In claims 9 and 23, "gene" is unclear because a "gene" implies a DNA sequence that exists in nature and includes coding and noncoding regions, as well as all regulatory sequences associated with expression. Since this does not appear to be Applicant's intention, the language "a DNA sequence of interest" is suggested. Or Applicant may recite the

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various components of the "gene" desired. All subsequent recitations of this language is also rejected.

- The preamble recites "compounds", however only one compound is extracted. Also, "commercially valuable compounds" lacks a comparative basis.
- In line 8 of claim 9, "the transgenic plant" lacks antecedent basis.
- In line 9, "fertilizing" is unclear because it can mean adding a nutritional  supplement or a sexual pollination.
- In line 14, "the recombinase" lacks antecedent basis. 
- In line 16, "economical quantities" is unclear because the metes and bounds of this claim can not be determined.

Clarification and/or correction is required.

***Claim Rejections - 35 USC § 112-1 Enablement***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 9 and 20-24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of producing a compound that is not detrimental to the plant, is not enabling for a compound detrimental to the plant, The

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specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicant claims any compound produced by a structural gene, where the compound is detrimental to the plant, expressing this compound, and extracting this compound in economic quantities.

Applicant teaches a glucuronidase and a bar resistance gene and expressing these genes, which are benign to the plant, a transformed plants. Applicant teaches extracting the glucuronidase for analysis of expression levels.

The state of the art is that one skilled in the art can readily make DNA constructs containing a structural gene encoding a compound, transform these into plants and express them with a reasonable expectation of success. However, expressing structural genes encoding a compound detrimental to the plant, such as barnase, is more unpredictable. Barnase is compound detrimental to the plant and expression is lethal to cells and tissues in which it occurs. Therefore expression of the gene encoding this detriment compound must be regulated in order to avoid killing all cells expressing it. (see Gutterson, US 6,392,119, column 14, lines 40-55). Recombinase mediated excision of appropriately flanked DNA sequences is variable and yields chimeric phenotypes having both recombined and unrecombined DNA (Gidoni, D. et al, Supplement to Plant Molecular Biology Reporter 18:2, S 03-40; ISPMB abstracts, June 18-24, 2000)(U). Recent studies (Gidoni, D et al (2001) Euphytica 121: 145-156. see pages 146 and 152) of embryonal recombination and germline inheritance of

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recombined tobacco loci show variable recombination efficiencies. Vergunst (Nucleotide. Acids. Research, 1998, vol 26, pages 2729-2734, see all of page 2733) shows unpredictability using the recombinase system as evidenced by instability of recombinants and phenotypic "escapes". The claimed methods require use of site-specific recombination systems to delete appropriately flanked DNA sequences.

Therefore, without further guidance, it is unpredictable that one skilled in the art would be able to express in a plant a structural gene encoding a compound detrimental to the plant, as Applicant has provided no guidance on how to predictably eliminate inoperable embodiments from a virtually ad infinitum of possibilities other than by random trial and error, which is excessive experimentation and an undue burden.

Applicant claims extracting a compound detrimental to the plant, and "in economic quantities". Since "in economic quantities" is undefined, it is impossible to determine what this term means, and claims to economic quantities are considered nonenabled. *maintain*

In view of the breadth of the claims (any plant, any compound detrimental to the plant, any extraction, and extraction in economic quantities), the lack of guidance in the specification, the lack of working examples, undue trial and error experimentations would be required to enable the invention as commensurate in scope with the claims.

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***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 9 and 20 – 24 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Kilby, NJ et al; (1995) Plant Journal 8: 637-652 (AR), in view of Odell et al (AA) and Kilby, NJ et al (1993) Trends in Genetics, 9: 413-421, for reasons of record.

Applicant has amended claim 9 to recite “expressing the compound detrimental to the plants and extracting the compound in economical quantities”.

Applicant traverses, stating primarily that the pending claims are directed to the production of economic quantities of a detrimental compound.

Applicant's traversal has been considered and is unpersuasive because although Applicant has amended the claims to recite “extracting the compound in economical quantities”, this limitation is given no patentable weight because of the lack of clarity of what these terms mean. (See 112.1 and 112.2 discussions above).

***Remarks***

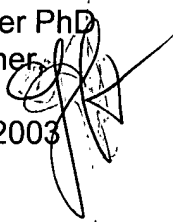
8. No claim is allowed.

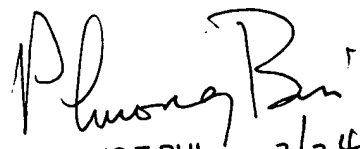
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 703-308-7023. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Georgia Helmer PhD  
Patent Examiner  
Art Unit 1638  
February 24, 2003



  
PHUONG T. BUI  
PRIMARY EXAMINER 2/24/03